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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,029	07/26/2000	PETER HIMMELSBACH	BEIERSDORF-6	5165

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EXAMINER	
PIERCE, JEREMY R	

ART UNIT	PAPER NUMBER
1771	

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/601,029	HIMMELSBACH ET AL.	
	Examiner	Art Unit	
	Jeremy R. Pierce	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10-15 and 17-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8,10-15 and 17-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed on February 24, 2005 has been entered. Claims 1, 2, and 36 have been amended. Claim 16 has been cancelled. Claims 1, 2, 4-8, 10-15, and 17-36 are currently pending. Applicant's amendment to claim 2 is sufficient to overcome the 35 USC 112 rejection set forth in section 3 of the last Office Action. Applicant's amendments to claims 1 and 2 are sufficient to overcome the 35 USC 103 rejections set forth in sections 5-9 of the last Office Action because the prior art references in those rejections do not teach sterilizing the adhesive composition.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 4, 5, 7, 8, 10-15, 17, 18, 20-30, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lucast et al. (U.S. Patent No. 6,479,073) in view of Merkle et al. (U.S. Patent No. 5,527,536) and Lucast et al. (U.S. Patent No. 5,407,717), and further in view of Koketsu et al. (U.S. Patent No. 5,547,223).

Lucast et al. disclose a medical tape for use on human skin (column 1, lines 5-20). Lucast et al. teach the substrate layer for the tape may be a nonwoven fabric

including stitch-bonded fabrics (column 3, line 2). The adhesive composition may comprise a styrene block copolymer (column 4, lines 17-21).

Lucast et al. do not teach a pharmacologically active agent to be present in the adhesive composition. Merkle et al. disclose a medical patch for controlled release of pharmacologically active agents (Abstract). The adhesive comprises a block copolymer that comprises polystyrene for one block and a mixture of ethylene and butylenes for another block (Abstract). It would have been obvious to a person having ordinary skill in the art at the time of the invention to incorporate a pharmacologically active agent into the tape of Lucast et al. in order to provide the tape with an enhanced medical function, as taught by Merkle et al.

Lucast et al. do not teach sterilizing the adhesive composition. The '717 Patent teaches that adhesive tapes that are used on human skin must be sterilized (column 11, lines 5-10). It would have been obvious to a person having ordinary skill in the art at the time of the invention to sterilize the Lucast et al. tape in order to make it safe for use on human skin, as taught by the '717 Patent.

With regard to claims 1, 21, and 22, Lucast et al. do not disclose how many stitches are present on backing layer of a stitch-bonded fabric per centimeter. Koketsu et al. teach the number of stitches in the backing layer would be a result effective variable that would alter the strength of the web, with more stitches supplying a stronger web (column 7, lines 16-32). It would have been obvious to one having ordinary skill in the art to provide 5 to 50 longitudinal stitches per centimeter in order to create a stitch-bonded fabric with a desired strength and rigidity provided by the stitches, since it has

been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With regard to claim 7, the backing material of Lucast et al. would be tearable by hand because it is used as medical tape. With regard to claims 8 and 24, Merkle et al. disclose the active substance is present in an amount between 2.5 and 25% by weight (Abstract). With regard to claim 11, Lucast et al. disclose using foaming agents in the adhesive (column 5, line 19). With regard to claim 12, Lucast et al. teach the adhesive may be discontinuously coated to the backing material (column 1, line 48). With regard to claims 13 and 35, Merkle et al. teach applying the adhesive by spraying (column 5, lines 1), but the limitation of the adhesive being sprayed on (for continuous coatings) or printed on (for discontinuous coatings) is a processing limitation that would not materially alter the claimed product. With regard to claim 14, Lucast et al. teach applying adhesive in a dot pattern (column 10, line 62). With regard to claims 17 and 18, Lucast et al. disclose the backing incorporate a low adhesion backside layer opposite the side where adhesive is located (column 3, lines 11-18). This layer would also cover the backing material according to claim 20. With regard to claim 33, Lucast et al. disclose the adhesive may comprise up to 20% of polymer material that is not a copolymer (column 4, lines 35-42). With regard to claim 36, the '717 Patent teaches sterilizing by gamma radiation (column 11, lines 9-10).

With regard to claim 4, although Lucast et al. do not explicitly teach the limitation of the compression force generated by the backing material at an elongation of 20 to 70%, it is reasonable to presume that said limitations are inherent to the invention.

Support for said presumption is found in the use of similar materials (i.e. polyester) and in the similar production steps (i.e. stitch-bonded nonwoven) used to produce the medical tape. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, it would have been obvious to one having ordinary skill in the art to provide a compression force of from 0.2 N/cm to 10 N/cm at an elongation of from 20 to 70% in order to create a medical tape with the desired strength, elongation, and break properties that are known in the art to be adjustable.

With regard to claims 5 and 23, Lucast et al. do not disclose a basis weight for the backing material. It would have been obvious to a person having ordinary skill in the art to provide a stitch-bonded nonwoven with a basis weight of between 10 and 350 grams per square meter in order to make the tape with a usable rigidity desired in the field of medical tapes for use on human skin.

With regard to claims 10, 25, and 26, Although Lucast et al. do not explicitly teach the limitations of dynamic-complex glass transition temperatures at a frequency of 0.1 rad/s, it is reasonable to presume that said limitations are inherent to the invention. Support for said presumption is found in the use of similar materials (i.e. adhesive composition comprising styrene block copolymers) and in the similar production steps (i.e. coating the adhesive on a stitch-bonded fabric) used to produce the medical tape. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, it would have been obvious to one having ordinary skill in the art to use adhesive with the claimed glass transition temperatures in order to provide the optimal amount of tackiness for use as a medical tape. Note *In re Best*, 195 USPQ 433,

footnote 4 (CCPA 1977) as to the providing of this rejection under 35 USC 103 in addition to the rejection made above under 35 USC 102.

With regard to claims 15, 27, and 28, Lucast et al. do not disclose the weight per unit area of the adhesive on the backing material. The amount of adhesive is a result effective variable that would affect the degree of adhesion the tape would have to the skin. It would have been obvious to one having ordinary skill in the art to provide between 130 and 500 grams per square meter of adhesive in order to create a medical tape with the optimum amount of adhesion property fit for its intended use on human skin, since it has been held that optimization of a result effective variable involves only routine skill in the art.

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lucast et al. in view of Merkle et al. and the '717 Patent as applied to claim 1 above, and further in view of Wildeman et al. (U.S. Patent No. 3,967,472).

Lucast et al. do not disclose the stitches of the fabric to be formed from loops from the fibers of the web. Wildeman et al. disclose that stitch-bonded fabrics may be stitched with the loops from the web (column 3, lines 40-68). It would have been obvious to a person having ordinary skill in the art at the time of the invention to stitch the fabric of Lucast et al. with loops from the web in order to avoid using extra stitching thread, as taught by Wildeman et al.

5. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lucast et al. in view of Merkle et al., the '717 Patent, and Koketsu et al. as applied to claim 1 above, and further in view of Bodenschatz et al. (U.S. Patent No. 6,074,965).

Lucast et al. do not teach reinforcing fibers in the nonwoven backing layer. Bodenschatz et al. teach a medical material that is supported with high-strength fibers with a maximum tensile strength over 60 cN/tex (Abstract). It would have been obvious to one having ordinary skill in the art to reinforce the stitch-bonded nonwoven web of Lucast et al. with high-strength fibers in order to create a tape with increased strength, as taught by Bodenschatz et al.

6. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lucast et al. in view of Merkle et al., the '717 Patent, and Koketsu et al. as applied to claim 1 above, and further in view of Seabold et al. (U.S. Patent No. 4,315,047).

Lucast et al. do not disclose coating the backing material with metallic substances. Seabold et al. teach that adhesive tapes may be coated with metal vapor on the backside as a means of rendering the tape opaque (column 6, lines 65-68). It would have been obvious to one having ordinary skill in the art to add metal vapor to the backing of Lucast et al. in order to make the tape non-transparent, as taught by Seabold et al.

7. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lucast et al. in view of Merkle et al., the '717 Patent, and Koketsu et al. as applied to claim 1 above, and further in view of Kantner et al. (U.S. Patent No. 5,489,624).

Neither Lucast et al. nor Merkle et al. teach incorporating pharmacologically active agents as not in co-mixture with the adhesive. Kantner et al. teach that adhesive materials in the medical field can frequently be used to transport drugs through the skin (Abstract). Kantner et al. disclose several examples of biologically active material that

would exist in particle form that can be incorporated into the adhesive (column 9, lines 28-41). It would have been obvious to a person having ordinary skill in the art at the time of the invention to incorporate active agents that are not in co-mixture with the adhesive composition in the medical tape of Lucast et al. in order to provide various healing properties to the tape, as taught by Kantner et al.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 2, 4-8, 10-15, and 17-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,555,730 to Albrod et al. in view of Merkle et al. (U.S. Patent No. 5,527,536).

Albrod et al. claims a backing material for medical purposes that is similar to the current application. Albrod et al. does not recite a pharmacologically active agent to be present in the adhesive. Merkle et al. disclose a medical patch for controlled release of

pharmacologically active agents (Abstract). The adhesive comprises a block copolymer that comprises polystyrene for one block and a mixture of ethylene and butylenes for another block (Abstract). It would have been obvious to a person having ordinary skill in the art at the time of the invention to incorporate a pharmacologically active agent into the tape of Albrod et al. in order to provide the tape with an enhanced medical function, as taught by Merkle et al.

Response to Arguments

10. Applicant's arguments with respect to claims 1 and 2 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant argues that Albrod et al. do not teach sterilizing the adhesive composition. However, claim 27 of that Patent suggests to one of ordinary skill that the tape is sterilized with gamma radiation. If not anticipated, it would at least be obvious to a person having ordinary skill in the art to sterilize the tape with gamma radiation.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy R. Pierce whose telephone number is (571) 272-1479. The examiner can normally be reached on Monday-Friday between 9am and 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JRP

Jeremy R. Pierce
March 28, 2005

ELIZABETH M. COLE
PRIMARY EXAMINER